FDA Public Health Web Notification*:
Complications Related to the Use of Bone Cement in Treating Compression Fractures of the Spine

Over the last decade, several types of complications have been reported in literature and to FDA following the use of polymethylmethacrylate (acrylic) bone cements to treat compression fractures of the spine. Labeling of marketed bone cements at the present time does not address use of this product to treat spinal compression fractures, nor does it address possible complications associated with this use. This document is intended to notify you of the types of reported complications associated with this use of bone cement.

Reported complications include serious injuries and deaths. Complications that relate specifically to the leakage of bone cements include soft tissue damage and nerve root pain and compression. Other reported complications generally associated with the use of bone cements in the spine include pulmonary embolism, respiratory and cardiac failure, abdominal intrusions/ileus, and death.[1-10] Each of these types of complications has been reported in conjunction with use of bone cements in both vertebroplasty and kyphoplasty procedures, two different techniques that employ bone cement to treat spinal compression fractures. Current information is insufficient to establish overall complication rates for either of these procedures or to distinguish the types and incidence of complications associated with the use of bone cements in each type of procedure.

Current Status

In the absence of labeling addressing use of bone cements to treat compression fractures of the spine, we encourage physicians to be aware of considerations and recommendations described in the literature and by professional organizations regarding patient selection, treatment techniques, potential complications, and patient monitoring when considering the use of bone cements in procedures to treat such fractures. [5,11-15]

Because more study would be beneficial, we are currently working with professional organizations and manufacturers of orthopedic devices to develop a basis for evaluating the safety and effectiveness of bone cements used to treat compression fractures of the spine. Some manufacturers have now received approval to conduct clinical studies to address the safety and effectiveness of bone cements used in this way. Until such studies are complete and results are submitted to FDA, information available to us is too limited to perform, and we do not intend this notice to be, an assessment of the safety and effectiveness of bone cements used to treat compression fractures of the spine, the risks and benefits of this use of bone cement, or the surgeries that involve it.

Background

According to the National Osteoporosis Foundation, about 700,000 vertebral fractures occur annually; approximately 270,000 of these fractures are painful and clinically

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diagnosed. Most patients are treated non-operatively, but some do not respond to conservative treatment and are left with persistent pain and limited mobility. These patients are potential candidates for vertebroplasty or kyphoplasty procedures, two invasive procedures that use bone cement to treat spinal compression fractures.

There are differences in technique between vertebroplasty and kyphoplasty procedures, as well as among practitioners of each procedure, including differences in the selection, modification, and application of bone cements.

Vertebroplasty, developed in the 1980s, involves the percutaneous injection of a mixture of polymethylmethacrylate bone cement and a contrast agent, typically barium sulfate, into the vertebral bodies using fluoroscopic and/or computed tomography guidance.[1-17] Early vertebroplasty procedures were primarily performed to alleviate pain and to stabilize fractured bone in patients with hemangiomas, malignant metastases, or other types of tumors of the spine.

Kyphoplasty, developed in the 1990s, involves introducing a surgical instrument into the vertebral body, with the intent to elevate or expand the vertebra.[3, 9, 18-20] Once this instrument is withdrawn, the space created is then filled with the bone cement mixture. By reducing and fixing the fracture in this way, kyphoplasty procedures may correct deformity and/or restore body height.

Acrylic bone cements have been used for many years for the fixation of metal and plastic prostheses in joint replacement and less frequently in the fixation of pathological fractures. These cements, however, have not been specifically evaluated for the treatment of spinal compression fractures. Existing cements designed for other uses are generally modified for use in treating spinal compression fractures. Modifications to cements may vary from physician to physician and among procedures. These types of modifications may include increasing the amount of contrast agent to improve x-ray visualization and changing the consistency and handling properties to address procedural goals (including changing the method of preparing the cement without altering its ingredients). To date, there are no standardized formulations, biomechanical standards or safety guidelines for the types or amounts of radio-opaque or other additives used, or for methods of preparing bone cement for use in the spine. The effects of modified bone cements on the spine and surrounding soft tissues have not been adequately studied to support marketing applications.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices, including bone cement. We request that you follow the procedures established by your facility for such mandatory reporting.

We also encourage you to report bone cement malfunctions. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's

voluntary reporting program. You may submit reports to MedWatch one of four ways: online at http://www.accessdata.fda.gov/scripts/medwatch/ ; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

FDA Contact

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Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

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